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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,780	05/20/2005	Akihiko Kitajima	2005-0265A	8813

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/526,780	Applicant(s) KITAJIMA ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 5-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3-8-05; 4-13-06</u> | 6) <input type="checkbox"/> Other: _____ |

A Preliminary Amendment filed March 8, 2006 is acknowledged. Updated priority information is noted. Claims 1-10 are presented.

Applicants' Response filed August 9, 2006 to the Restriction Requirement mailed July 10, 2006 is further acknowledged. Applicants have elected Group II, drawn to methods for promoting the movement of the digestive tract comprising administering 4-amino-5-chloro-2-methoxy-N-[(2S,4S)-2-hydroxymethyl-4-pyrrolidinyl]benzamide, claims 3 and 4. No traversal of the Restriction Requirement is noted. Accordingly, acquiescence thereto is concluded. 37 CFR 1.111(b).

Claims 1, 2 and 5-10 are withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Re-affirmation of the election is requested when Applicants respond to this Office Action.

Information Disclosure Statements filed March 8, 2005 and April 13, 2006 are further acknowledged and have been reviewed.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants have failed to define the invention properly and clearly.

With respect to the term "ameliorant" in claims 3 and 4, it is unclear whether or not 4-amino-5-chloro-2-methoxy-N-[(2S,4S)-2-hydroxymethyl-4-pyrrolidinyl]benzamide is the ameliorant, or the only ameliorant. It is unclear whether or not the term has any probative value in claim 3.

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With respect to the recitation "which has high binding affinity for a serotonin receptor 4 (5HT₄)", it is unclear to what the limitation refers. The ameliorant? The compound? An acid addition salt?

It is noted a limitation in claim 3 recites "does not cause arteritis **and** thrombus formation, while a similar limitation in claim 4 recites "while avoiding occurrence of arteritis, thrombus formation **or** encephalomalacia".

Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fujiwara et al., U.S. Patent 5,143,935.

Fujiwara teaches compounds of formula I, wherein R₁ and R₂ may be hydrogen or alkyl. 4-Amino-5-chloro-2-methoxy-N-[(2S,4S)-2-hydroxymethyl-4-pyrrolidinyl]benzamide is included in the disclosure. The compounds have "a promoting activity of the gastrointestinal tract" and especially to the stomach. See column 1, lines

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50-64 and column 2, lines 43-45. All stereoisomers are included in the disclosure. See column 2, lines 26-31. Promoting activity to gastric emptying is highlighted in column 3. Although the example presented in column 14 is drawn to a compound that differs from that presently claimed by an ethyl group in place of a hydrogen atom on the nitrogen of the pyrrolidiny ring, in terms of a promotion of the activity of the gastrointestinal tract, Fujiwara teaches an equivalence among the groups on the pyrrolidiny ring and the optical isomers. An absence of cardiovascular adverse effects, such as thrombus formation, arteritis or encephalomalacia, is an inherent property of 4-amino-5-chloro-2-methoxy-N-[(2S,4S)-2-hydroxymethyl-4-pyrrolidiny]benzamide.

The reference teaches a small genus which places a claimed species in the possession of the public. See *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 28, 2006


Phyllis G. Spivack
**PHYLLIS SPIVACK
PRIMARY EXAMINER**